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	09/813,329	03/20/2001	Pamela M. Carroll	D0016 NP	1246	
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	STEPHEN B. DAVIS			EXAMI	EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

•	· · · · · · · · · · · · · · · · · · ·	Application No.	Applicant(s)				
•	•	09/813,329	CARROLL ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Jegatheesan Seharaseyon	1647				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) 🖂	Responsive to communication(s) filed on 30 C	<u> </u>					
2a) <u></u>	, —	s action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	Disposition of Claims						
4)⊠	4) Claim(s) 41-63 is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)⊠							
7)⊠	7)⊠ Claim(s) <u>41</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement. Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority (ınder 35 U.S.C. §§ 119 and 120						
13)	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)	a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
* 5	 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
_a	_a) _ The translation of the foreign language provisional application has been received.						
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s)							
1) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) 7	5) Notice of Inform	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)				

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DETAILED ACTION

1. Applicants election without traverse of Group I, claims 1-5, 7, 8, 11, 14-26, 29, 33 and 38, drawn to nucleic acid encoding a polypeptide, a vector and a host cell in Paper No.: 9 (10/30/02) is acknowledged. Applicant has elected to cancel all the pending claims and provided a new set of claims that are readable on the elected invention. Applicants have further elected the nucleotide sequence of SEQ ID No: 5 and the nucleic acids that encode SEQ ID No: 6. Claims 41-63 are pending.

Drawings

2. The drawings have been objected to by the draftsperson (see attached 948). Appropriate correction is required.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that,

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normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

3. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

4. Claim 41(b) and (c) is objected to because of the following informalities: The SEQ ID number of the polypeptide sequence is No. 6. Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41-63 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

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The instant claims are directed to a nucleic acid sequence of SEQ ID NO: 5 and the nucleic acid encoding the polypeptide of SEQ ID No: 6 belonging to an alleged novel drosophila tumor necrosis factor class molecule. These claims are drawn to an invention with no apparent or disclosed patentable utility. The applicant claims that the transcripts corresponding to DmTNF are expressed highly in Drosophila embryos and larvae with lower levels observed in adult tissue (page 179-180 and Fig. 10). The allegedly novel DmTNF polynucleotides were identified based on BLAST searching (Example 1). The instant application does not disclose the biological role of this protein or its significance. Novel biological molecules lack well-established utility and must undergo extensive experimentation.

The applicant claims that the DmTNF apparently encodes a 409 amino acid protein (Figure: 3A-C) and contains structural features characteristic of TNF protein (Figure: 3B). This is presumably because of sequence homology between the instant invention (DmTNF) and other TNF domain containing proteins (page 176). However, the homology of a peptide is not a reliable indicator for the functional characteristics (see Scott et al. 1999). The Scott et al. reference, based on the amino acid sequence homology, predicted that the Pendred syndrome gene to be a sulfate transport protein. However, the results demonstrated that the protein was a chloride-iodide transporter protein (see abstract). Furthermore, since the specification does not disclose any methods or working examples that demonstrate the polynucleotide and polypeptide of the instant application exhibit activities similar to other TNF like protein, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the

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instant application as a TNF like protein. Additionally, the specification of the instant application does not teach the skilled artisan which domains of transporter protein sequence are structurally related to other amino acid transporter proteins. One skilled in the art would not know the utility and function of DmTNF protein, even if it was a putative TNF like protein because, as discussed in the related art above and the specification of the instant application, neither the prior art nor the specification provides for the physiological significance of the claimed amino acid drosophila TNF like protein.

There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point -

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where specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to nucleotides and peptides, which have a yet undetermined function or biological significance. Applicants have disclosed that they are in possession of nucleic acid sequence of SEQ ID NO: 5 and the nucleic acid encoding the polypeptide of SEQ ID No. 6. In addition, Applicant also claims the developmental regulation of DmTNF message (page 179-180, Fig. 10). However, there is no actual and specific significance which can be attributed to said polypeptides and the polynucleotides identified in the specification, except the prophetic recitation of potential uses, which include the use of this TNF like protein and the nucleotides in screening methods for identifying agonist and antagonists of the polynucleotides and polypeptides of the present invention (page 1, line 18-24). In addition, to methods of genetically modifying Drosphila or cultured cells to express or mis-express DmTNF, DmTNFv1, or DmTNFv2, the invention also relates to the use of such modified insects or cells to characterize DmTNF activity, identify TNF-like genes and or genes implicated in modulating TNF, characterize TNF signaling pathways, and/or to identify modulators of DmTNF activity (ibid). For this reason, the instant invention is incomplete. Since, neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed protein, there is no immediately obvious patentable use for it. In addition, the instant specification does not disclose a "real-world" use for said polypeptides and polynucleotides,

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except the prophetic recitation of potential uses, which include possible biological and therapeutic uses. Also, there are no working examples that demonstrate any specific utility. Thus, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Therefore, since the peptide of the invention is not supported by a specific and substantial asserted utility or a well established utility, then the composition comprising the polypeptide and a carrier also are not supported by a specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-63 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 41-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

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The specification discloses nucleotides of SEQ ID No: 5, nucleotide encoding SEQ ID No: 6 and nucleotide allegedly encoding the TNF domain of the DmTNFv2 polypeptide (Fig. 3A-C). These disclosures meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the specification does not disclose any other nucleotides which are either complimentary to or hybridizing to a nucleic acid comprising the nucleotide sequence of SEQ ID No: 5 or fragments of SEQ ID NO: 5 or nucleotides encoding a protein comprising the amino acid of SEQ ID No: 6 or nucleotide encoding polypeptide fragments consisting of SEQ ID NO: 6. The specification also does not disclose any other nucleotides which is at least 80.0% identical to the nucleotide sequence of SEQ ID No: 5 or fragments of SEQ ID NO: 5 or nucleotides encoding a protein comprising the amino acid of SEQ ID No: 6 or nucleotide encoding polypeptide fragments consisting of SEQ ID NO: 6 or sequences containing deletion or substitutions. The claims as written, however, encompass various nucleotide sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 41,46, 48, 50, 51, 58 and 59-63. The specification does not provide written support for the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in

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the art to recognize that [he or she] invented what is claimed" (See Vas-Cath at page 1116).

With the exception of the isolated nucleotide sequence of SEQ ID No: 5, nucleotide sequence encoding SEQ ID No: 6 and nucleotide sequence allegedly encoding the TNF domain of the DmTNFv2 polypeptide (Fig. 3A-C) the skilled artisan cannot envision all the detailed chemical structures of the claimed nucleotide sequences, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only an isolated nucleotide sequence of SEQ ID No: 5, nucleotide sequence encoding SEQ ID No: 6 and nucleotide sequence allegedly encoding the TNF domain of the DmTNFv2 polypeptide (Fig. 3A-C) but not the full breadth of the claims encompassing the various fragments meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of the various polynucleotide sequences set forth in claims 41,46, 48, 50, 51, 58, 59-63.

8. Claim 41 recites a "mature polypeptide", however, the instant specification fails to describe that portion of a protein, which is the "mature" portion. Applicant is

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claiming a very specific species, which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature polypeptide" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved in vivo, as well as being differentially processed based on which in tissue the protein is expressed. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of the "mature polypeptide"; therefore, the specification does not provide an adequate written description of a mature protein, and thus the claimed invention, to the extent that it reads upon mature protein was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Further, the structure of the "mature" protein will be host cell specific; i.e.

E. coli will produce a form of the protein which is the "mature" form in that host where as an insect host may produce a different form which will also be a "mature" form. Therefore, the instant specification fails to describe "mature" because this is a specific structure for which there is insufficient evidence to establish that the invention was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

9. Claims 41,46, 48, 50, 51, 58 and 59-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for an isolated nucleotide sequence of SEQ ID No: 5, nucleotide sequence encoding SEQ ID No: 6 and nucleotide sequence allegedly encoding nucleotide allegedly encoding the TNF domain of the DmTNFv2 polypeptide (Fig. 3A-C), does not reasonably provide enablement for all possible nucleotide sequences that are either complimentary to or hybridizing to a nucleic acid comprising the nucleotide sequence of SEQ ID No: 5 or fragments of SEQ ID NO: 5 or nucleotide sequence encoding a protein comprising the amino acid of SEQ ID No: 6 or nucleotide sequence encoding polypeptide fragments consisting of SEQ ID NO: 6. The specification is not enabled for any other nucleotide sequence which is at least 80.0% identical to the nucleotide sequence of SEQ ID No: 5 or fragments of SEQ ID NO: 5 or nucleotides encoding a protein comprising the amino acid of SEQ ID No: 6 or nucleotide encoding polypeptide fragments consisting of SEQ ID NO: 6 or sequences containing deletion or substitutions or the various modifications contemplated by the Applicant. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Despite knowledge in the art for producing fragments of a given polypeptide with amino acid deletions, insertions or substitutions the specification fails to provide any guidance regarding the changes/modifications contemplated and yet retain the function of the all-possible variations or fragments with activity or modifications claimed in the instant invention. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. The problem of predicting protein structure from sequence data and in turn

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utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells. 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume

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the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. Therefore, predicting which nucleotide sequence encoding the variants would retain the functions of the DmTNF protein is well outside the realm of routine experimentation. Thus, undue amount of experimentation would be required to generate changes/modifications of the nucleotides contemplated and yet retain the function of the DmTNF variant proteins claimed.

Applicants have not taught how one of skill in the art would use the full scope of polynucleotide sequences encompassed by the invention of claims 41,46, 48, 50, 51, 58 and 59-63. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences. Given the breadth of claims 41,46, 48, 50, 51, 58 and 59-63 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior at of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. 10a. Claim 41is rejected as vague and indefinite for reciting the term "capable". 10b. Claim 41 isindefinite because the claim recites the "....under stringent....". This is relative, and the art does not recognize a single set of conditions for hybridization. Therefore, the metes and bounds of the claim are unclear. 10c. Claim 54 is rejected as being indefinite because the claim recite a recombinant method for producing a polypeptide comprising insertion of the polynucleotide of claim 41 into a host cell. Claim 41(e) recites a polynucleotide consisting of "a nucleotide sequence that is completely complementary to a nucleotide sequence of (a)-(d)". It is not clear how the polynucleotide complements of claim 41(e) produce the polypeptide disclosed in the instant application. A complement is a sequence of nucleotide bases in one strand of a DNA or RNA molecule that is exactly complementary (adenine-thymine, adenineuracil, or guanine-cytosine) to that on another single strand.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 41-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Celniker et al (AC005974, 1998).

The instant invention is directed to nucleic acids encoding a polypeptide, a vector and a host cell.

Celniker et al. describe a nucleotide sequence from drosphila (AC005974). This nucleotide sequence has 99.8% identity over nucleotides 5-806 of SEQ ID NO: 5 of the instant invention (see Appendix A). This sequence is capable of hybridizing SEQ ID NO: 5, fragments of SEQ ID NO: 5 and the nucleotide encoding SEQ ID NO: 6. Therefore, the disclosure of Celniker et al., anticipates claims 41, 51, 58 and 62. Claims 53, 54, 55,56, 57, 59, 60 and 61 rejected insofar as they depend on rejected claims 41, 51 and 58.

12. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS January 27, 2003

JEFFREY STUCKER
PRIMARY EXAMINER